

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

**Nifedilong 30 mg Prolonged Release Tablets**

**Nifedilong 60 mg Prolonged Release Tablets**

Each prolonged release tablet of Nifedilong 30 mg contains:

Nifedipine 30 mg

Each prolonged release tablet of Nifedilong 60 mg contains:

Nifedipine 60 mg

For inactive ingredients and allergens in the preparation - see section 6 “Additional information” and the section “Important information about some ingredients of the medicine”.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar. This medicine is not intended for use in children and adolescents under the age of 18.

**1. What is the medicine intended for?**

The medicine is intended for treatment of chronic and stable angina, and for treatment of hypertension.

**Therapeutic class:** calcium channel blockers.

**The mechanism of action of this medicine:**

For angina - relaxation and expansion of the arteries supplying the heart. This allows more blood and oxygen to reach the heart and decreases the strain on it. Your angina attacks will be less severe and less frequent if there is less strain on the heart.

For hypertension - relaxation and expansion of the blood vessels. This makes the blood flow more easily and lowers blood pressure. Lower blood pressure reduces the strain on your heart.

**2. Before using the medicine:**

**❗ Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient nifedipine, or to any similar medicine of the dihydropyridines group, or to any of the other components the medicine contains (see section 6).
- You had a heart attack in the past month.
- You have a sudden angina attack. This medicine will not relieve symptoms of angina quickly.
- You have unstable angina.
- You are taking an antibiotic called rifampicin.
- You have a liver disease that prevents your liver from working properly.
- You have bowel inflammations (inflammatory bowel disease, e.g.: Crohn's disease).
- You have, or have had in the past, bowel obstruction or narrowing.

- You have had an obstruction in the esophagus (the tube connecting the throat to the stomach).
- You have a narrowing of the aortic heart valve.
- You previously collapsed due to a cardiac problem (cardiogenic shock), during which you became breathless, pale and you felt a cold sweat and dry mouth.
- You have had a “Kock pouch” bowel surgery (a surgically constructed intestinal reservoir with an opening for drainage through the abdominal wall).
- Your blood pressure keeps rising despite treatment with the medicine (malignant hypertension).

**❗ Special warnings regarding the use of the medicine: Before treatment with Nifedilong, inform the doctor if:**

- You have low blood pressure and are taking Nifedilong for treatment of angina. The medicine may cause further drop in blood pressure.
- You have heart diseases, where the heart is unable to cope with increased effort (poor cardiac reserve).
- You are pregnant.
- You are breastfeeding. If you need to take Nifedilong, you should stop breastfeeding before you start to take this medicine.
- You have diabetes. The dosage of your antidiabetic medicines may need to be adjusted. If you have any questions about this, ask your doctor.
- You are on kidney dialysis. If you are suffering from very high blood pressure with small blood volume, treatment with Nifedilong may cause a sharp drop in blood pressure.
- You are about to give a urine sample. Nifedilong may interfere with the results of certain urine tests.
- You are about to have an x-ray with barium (contrast agent). Nifedilong may affect the results of the test.
- You are a man who is unable to father a child by in vitro fertilization. Medicines like Nifedilong may impair sperm function.

**Before taking the next dose, inform the doctor if:**

- The angina worsens during treatment with the preparation (stronger pain or higher frequency) within a few hours or days. You may be advised to stop taking Nifedilong.
- You had chest pains after taking your first dose of Nifedilong. Your doctor may wish to change your treatment.
- You notice increased shortness of breath.
- You notice swelling of the ankles.

**❗ Children and adolescents:**

This medicine is not intended for children and adolescents under the age of 18, since information about the efficacy and safety of the preparation in this population is limited.

**❗ Drug interactions:**

**If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell the doctor or the pharmacist.** Especially inform the doctor or pharmacist if you are taking:

- Other medicines for treatment of high blood pressure.
- Rifampicin (an antibiotic) (see also “Do not use this medicine if”).
- Cimetidine (for treatment of stomach ulcers).

- Digoxin, diltiazem, quinidine or beta-blockers (for treatment of heart conditions).
- Quinupristin/dalfopristin (a combination of antibiotics).
- Phenytoin, carbamazepine or valproic acid (for treatment of epilepsy).
- Cisapride (for treatment of reduced motility of the esophagus and stomach).
- Magnesium sulfate injections during pregnancy (may cause a sharp drop in blood pressure).
- Erythromycin (an antibiotic).
- Ketoconazole, itraconazole or fluconazole (anti-fungal medicines).
- Indinavir, nelfinavir, ritonavir, saquinavir or amprenavir (for treatment of AIDS (HIV)).
- Fluoxetine, nefazodone (for treatment of depression).
- Tacrolimus (for prevention of rejection of transplanted organs).
- Phenobarbital (usually used for treatment of insomnia or anxiety).
- ❗ **Use of the medicine and food:**
  - The medicine may be taken with or without food.
  - **Do not drink grapefruit juice or eat grapefruit while taking the medicine.**
  - Do not start taking the medicine within 3 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice during this time.
  - Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

**❗ Pregnancy, breastfeeding and fertility:**

If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before starting to use this medicine. You may be able to use the medicine, but only after your doctor has carefully considered it and allowed you to use this medicine.

Do not use this medicine if you are breastfeeding. If you need to use the medicine, you should stop breastfeeding before starting to use it.

**❗ Driving and operating machinery:**

The medicine may cause dizziness, weakness, fatigue or visual disturbances. Do not drive or operate machinery if you are experiencing these effects. These effects usually occur in the beginning of treatment with the preparation, after changing the type of tablets or when drinking alcohol.

**❗ Important information about some ingredients of the medicine:**

The medicine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

**3. How should you use the medicine?**

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be determined by the doctor only.

**Do not exceed the recommended dose.**

**Method of administration:**

The tablet should be swallowed whole with a glass of water. The medicine may be taken with or without food. The medicine should not be taken together with grapefruit juice.

The medicine should be taken every day at the same time, preferably in the morning.

**Crushing/halving/chewing**

Do not chew, the tablet is intended to be swallowed.

The tablet should not be halved or crushed.

Nifedilong is a prolonged-release tablet. Halving or crushing the tablet may lead to an overdose due to immediate release of the medicine.

You may notice what looks like a whole tablet in the toilet or in your stools. This is normal – it is the outer shell of the tablet, which is not digested by the body.

**If you accidentally took a higher dosage** you may suffer from signs of impaired consciousness up to loss of consciousness, hypotension, slowing or acceleration of heart rate, high blood sugar level, low blood oxygen levels, increased blood acidity (acidosis) and pulmonary edema.

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

**If you forgot to take the medicine** at the scheduled time, take the next dose immediately and continue taking the medicine at the regular time. After taking a dose, you should wait at least 12 hours before taking the next dose. Do not take a double dose in order to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.**

**If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.**

**4. Side effects:**

As with any medicine, using Nifedilong may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Contact your doctor immediately and do not take the next dose if you experience the following side effects, which may be the first signs of a potentially severe allergic reaction:

- A severe and sudden generalized allergic reaction, which in rare cases includes life-threatening shock (e.g.: breathing difficulties, drop in blood pressure, fast pulse), swelling (including life-threatening swelling of the airways).
- Other allergic reactions causing swelling under the skin (which may be severe and include life-threatening swelling of the throat).
- Rapid heartbeat (tachycardia).
- Shortness of breath (unknown frequency) or difficulty breathing.
- A mild to moderate allergic reaction.

- Itching (sometimes severe) and a rash.

**Contact your doctor immediately before continuing the treatment** if you are experiencing any of the following effects, which may be signs of a severe reaction:

- A skin reaction or blistering, peeling of the skin and/or mucosal reaction (in the mouth, nose, penis or vagina) (toxic epidermal necrolysis).

**Common side effects - side effects that occur in 1-10 out of 100 users:**

- Headache
- Flushing
- General malaise
- Constipation
- Swelling, particularly of the ankles and legs

**Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:**

- Abdominal pain
- Non-specific pain
- Chills
- Blood pressure drop when standing up (symptoms include fainting, dizziness, pounding heartbeats, blurry vision and occasionally confusion), fainting, irregular heartbeats (palpitations)
- Dry mouth
- Indigestion or upset stomach, flatulence, nausea
- Muscle cramps, joint swelling
- Sleep disturbances, anxiety or irritability
- Skin redness
- Nose bleeding, nasal congestion
- Sensation of dizziness (vertigo), migraine, dizziness
- Tremor
- Increased need to pass urine, pain or difficulty passing urine, difficulty in achieving or maintaining an erection (impotence)
- Blurry vision
- Temporary increase in certain liver enzymes

**Rare side effects - side effects that occur in 1-10 out of 10,000 users:**

- Pins and needles (paresthesia)
- Gum inflammation, tender or swollen gums, bleeding gums

**Side effects with unknown frequency (effects whose frequency has not yet been determined):**

- Stomach pain or distress caused by a mass of foreign material found in the stomach, which may require surgery for removal, difficulty swallowing, abdominal pain caused by bowel obstruction or bowel ulcers, vomiting
- A decrease in the number of white blood cells (leukopenia), a more severe decrease in granulocytes, a type of white blood cells (agranulocytosis)
- High levels of sugar in the blood (hyperglycemia)
- Decreased skin sensitivity to pain or touch (hypoesthesia)
- Drowsiness and somnolence
- Eye pain, chest pain (angina pectoris)
- Heartburn or indigestion (lower esophageal sphincter insufficiency)
- Yellowing of the skin or the whites of the eyes (jaundice)
- Sensitivity to light (an allergic reaction to sunlight)

- Small areas of raised rash due to bleeding in the skin (purpura)
- Muscle and joint pain
- Depression

These symptoms usually resolve when treatment with Nifedilong is stopped.

**If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not indicated in the leaflet, consult with the doctor.**

**Reporting side effects:**

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (Exp) appearing on the package. The expiry date refers to the last day of that month.

**Storage**

Store under 25°C in the original package in order to protect from light and moisture.

**6. Additional information**

**In addition to the active ingredient, the medicine also contains:**

**Tablet core composition:**

Talc, Povidone, Lactose monohydrate, Carbomer 974P, Hypromellose, Silica Colloidal Anhydrous, Magnesium Stearate.

**Tablet coating composition:**

Talc, Eudragit E, Hypromellose, Titanium Dioxide, Magnesium Stearate, Macrogol 4000, Ferric Oxide (Red).

**What does the medicine look like and what are the contents of the package:**

A prolonged-release tablet of Nifedilong 30 mg is a round, pale-red, biconvex tablet. Each pack contains blisters of 10 tablets. Amount of tablets in a pack: 10, 20, 30, 60 or 100. A prolonged-release tablet of Nifedilong 60 mg is a round, pale-red, biconvex tablet. Each pack contains blisters of 10 tablets. Amount of tablets in a pack: 10, 20, 30, 60 or 100.

Not all package sizes may be marketed.

**License holder/importer:** CTS Chemical Industries Ltd., 3 Hakidma st., P.O. box 385, Kiryat Malachi.

**Manufacturer:** Valpharma S.P.A., Republic of San Marino Via Ranco 112, Serravalle, Republic of San Marino

**Registration numbers of the medicine in the national drug registry of the Ministry of Health:**

137-89-31415-00, 137-21-31416-00

This leaflet was revised in 03/2025 in accordance with the Ministry of Health guidelines.

